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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,763	09/17/2001	Paul J. Thompson	11576.51USI1	8878

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EXAMINER	
WEBB, SARAH K	
ART UNIT	**PAPER NUMBER**
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/26/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/954,763	THOMPSON ET AL.	
	Examiner	Art Unit	
	Sarah K. Webb	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,23,25,26 and 28-36* is/are pending in the application.

4a) Of the above claim(s) *9,12,15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10,11,13,14,17-19,23,25,26,28-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-8,10,11,13,14,17-19, 23, 25,26, 28,29, and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,786,918 to Krivoruchko et al. ('918) in view of US Patent No. 6,168,617 to Blaeser et al.

'918 discloses a catheter that includes an outer shaft (26), inner shaft (24), fluid channel (68A-H), admission port (shown in Figures 3 and 15), stent (28) mounted on the distal region, and a spacer (62) comprising a plurality of "splines" disposed in the fluid channel. The spacer (62) can best be seen in cross-section in Figure 5 and is substantially similar to the spacer shown in Figure 5 of the application. Figure 2 illustrates that the spacer (62) extends a majority of the length of the catheter shafts (24,26). The admission port that extends through the sidewall of the handle in Figures 3 and 15 (column 6, lines 12-20) is similar to admission port (42) at the proximal end of the shaft disclosed in applicant's specification. The port is in communication with the fluid channel, as Krivoruchko explains that saline may be delivered to the lumen (column 6, lines 12-13), so the structure of the admission port disclosed by Krivoruchko is considered to meet the claim requirements. '918 discloses that the inner and outer shafts are slidable relative to one another (column 3, lines 35-37). As shown in Figure 2, a guide wire (82) may be disposed in the lumen of the inner shaft (24) (column 6, lines 13-14). The stent (28) is self-expanding and deployed by retraction of the outer shaft (26).

Krivoruchko fails to include discharge openings in the wall of the outer shaft near the proximal and distal ends of the stent mounting location. Blaeser discloses a catheter with a stent (48) mounted on a distal region of a shaft (14) and a retractable sheath (28). Figure 4 shows that apertures (52) may be formed in the outer sheath (column 6, lines 9-10), and a port (60) is in communication with a passageway in the catheter and the apertures of the outer sheath (column 5, lines 30-32 and 50-54). Some of the apertures may be located proximal or distal to the "stent mounting location", since the sheath (28) extends past both ends of the stent (48). Blaeser teaches that the apertures can enhance flexibility (column 6, lines 9-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include apertures proximal and distal the stent mounting region of the '918 device, as Blaeser teaches that an array of apertures in a retractable sheath of a stent delivery device can enhance flexibility.

Regarding claims 17 and 18, the spacer is considered to have a surface that is *capable of* being thermally bonded to another surface. No other structural characteristics are required by these claims.

2. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Krivoruchko ('918) in view of Blaeser, and further in view of US Patent No. 5,005,584 to Little.

The modified '918 device includes all the limitations of claim 30, except for a pressure measuring device. Little discloses a guide wire that measures fluid pressure and is capable of being used with the modified '918 device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the Little guide wire for the guide wire of the modified '918 device, as this

produces a combination that is capable of measuring fluid pressure within a passageway. This combination would provide the operator with the capability of detecting defects in the body passageway.

Response to Arguments

3. Applicant's arguments filed 10/19/06 have been fully considered but they are not persuasive. Applicant argues that the 103 rejection under Krivoruchko et al. ('918) in view of Blaeser et al. is not proper, because there is no motivation to combine or a reasonable expectation of success. This argument is based upon applicant's assertion that because Blaeser states that the sheath should be thin, a thin sheath would not be capable of retaining the self-expanding stent of Krivoruchko. Blaeser is simply relied upon for teaching that *apertures* can enhance flexibility of a stent retention sheath (column 6, lines 9-10). The thinness of the Blaeser sheath is irrelevant. Nonetheless, one of ordinary skill in the art would be capable of determining the thickness of the modified sheath that is required to retain the compressed configuration of the stent. The sheath of Blaeser is configured to retain a stent in a compressed configuration, which is similar to Krivoruchko, so the teaching of Blaeser to increase flexibility of the sheath is directly applicable to Krivoruchko.

Though applicant asserts that flexibility of an outer sheath that retains a stent, flexibility of a stent delivery catheter is widely known in the art to be an important feature, as this allows the stent to be maneuvered through tortuous vessels. Some of the apertures may be located proximal or distal to the "stent mounting location", since the sheath (28) extends past both ends of the stent (48).

Applicant also argues that the modified device does not have apertures proximal and distal to the "stent mounting location." The "stent mounting location" is

considered by the office to only include the area directly underlying the stent. As can be clearly seen in Figure 2 of Blaeser, the sheath (28) extends proximally and distally of the stent (48). Figures 4 and 5 of Blaeser illustrate the apertures (52) located along the length of the sheath (28). Therefore, the apertures of the modified Krivoruchko would be located proximally and distally of the "stent mounting region."

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SKW
12/15/06

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER